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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766
27367	7590	02/07/2006	EXAMINER	
WESTMAN CHAMPLIN & KELLY, P.A. SUITE 1400 - INTERNATIONAL CENTRE 900 SECOND AVENUE SOUTH MINNEAPOLIS, MN 55402-3319			HON, SOW FUN	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,721

Applicant(s)

REIMINK ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The 35 U.S.C. 102(b) and 103(a) rejections of claims 10-20 have been withdrawn due to Applicant's amendment dated 11/18/05.

Rejections Repeated

2. The 35 U.S.C. 103(a) rejections of claims 1-9, 31-32 have been repeated for the same reasons of record in the Office action dated 11/18/05.

New Rejections

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 depends on claim 10. Claim 10 recites "a polymer member covering the substrate, ... and wherein the polymer member contacts bodily fluids and separates the bodily fluids from the substrate." Yet claim 20 further recites "a diamond-like carbon coating over at least a portion of the polymer". Does the diamond-like carbon coating only cover a portion of the polymer member so that the polymer

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member still contacts bodily fluids and separates the bodily fluids from the substrate?

Then claim 20 should be amended to reflect that only a portion of the polymer member is covered by the diamond-like carbon coating.

Claim Rejections - 35 USC § 103

4. Claims 10-11, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenkei (US 4,597,767) in view of Reul (US 4,263,680) and Koppert (US 5,089,020).

Regarding claims 10, 15, Lenkei teaches a medical device which comprises a heart valve prosthesis (column 4, lines 39-45) comprising a flexible composite component comprising leaflets, wherein each leaflet comprises an inorganic substrate which comprises a metal foil (stainless steel, column 4, lines 19-25). The flexible component can be bent through a cross section of the flexible component (stainless steel foil). Lenkei fails to teach that at least a portion of the inorganic substrate is covered by a polymer member, wherein the polymer member contacts bodily fluids and separates the bodily fluids from the substrate.

However, Reul teaches that heart valve members advantageously comprise metal coated on both sides with blood-compatible synthetic material (column 4, lines 18-29). Reul fails to teach that the blood-compatible synthetic material is a polymer member.

However, Koppert teaches that the blood-compatible synthetic material is a polymer member for surfaces of an artificial heart, which are in contact with blood (polyurethane, column 4, lines 21-30) for the purpose of providing blood compatibility.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have covered the stainless steel foil of Lenkei with a blood-compatible polymer member, in order to obtain a heart valve member with blood compatibility, as taught by Reul and Koppert.

Regarding claim 11, Lenkei fails to teach the thickness of the metal foil.

However, Reul teaches that the heart valve member is preferably less than 300 microns (0.3 mm), which is within the claimed thickness range of less than about 500 microns, for the purpose of being able to react almost instantaneously to the quickly changing pressure gradients inside the heart chamber (column 3, lines 40-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the metal foil of Lenkei with a thickness of less than 500 microns, in order to obtain a heart valve member that can react almost instantaneously to the quickly changing heart chamber environment, as taught by Reul.

Regarding claims 16-19, Lenkei fails to disclose that the flexible composite component can be bent about 180 degrees without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 60 degrees for about 40 million cycles

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without significant structural failure; or that the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure.

However, the stainless steel foil of Lenkei (column 4, lines 19-25) is flexible and is expected to have the physical properties necessary to meet the limitations set forth above, as evidenced by Applicant's specification (page 14, lines 15-30), which teaches the same metal, stainless steel.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenkei in view of Reul and Koppert, as applied to claims 10-11, 15-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Lenkei in view of Reul and Koppert, has been discussed above, and fails to teach that the composite further comprises a diamond-like carbon coating over at least a portion of the polymer member.

However, Sumimoto teaches that a diamond-like carbon coating over the polymer provides good antithrombosis and durability properties (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a diamond-like carbon coating over at least a portion of the polymer member of Lenkei in view of Reul and Koppert, in order to obtain good antithrombosis and durability properties, as taught by Sumimoto.

Response to Arguments

6. Applicant's arguments with respect to claims 10-20 have been considered but are moot in view of the new ground(s) of rejection.
7. Applicant's arguments with respect to claims 1-9, 31-32 over Scott as the primary reference have been fully considered but they are not persuasive.
8. Applicant argues that in claim 1, the recitation of "a polymer covering all of the substrate" means that the polymer is in contact with all the surfaces of the substrate, and that Scott only teaches that the polymer sheath covers the outer surfaces of the stent with which the sheath is in contact with.

Applicant is respectfully apprised that the term "to cover" ordinarily means to conceal. Thus the sheath of Scott does cover all of the substrate. Furthermore, it is noted that the features upon which applicant relies (i.e., surfaces of the substrate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Applicant's arguments regarding the 35 U.S.C. 103(a) rejections over Scott as the primary reference are all directed to the validity of Scott as the primary reference, and are addressed above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

02/07/06

Harold Pyon

HAROLD PYON
SUPERVISORY PATENT EXAMINER

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2/6/06